Compliance Assistance Tool for Clean Air Act Regulations: Subpart GGG of40 CFR NESHAPS for Source Category Pharmaceutical Production

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LIST OF ACRONYMS

ACT	Alternative Control Techniques Information Document (EPA, 1994)
APCD	Air Pollution Control Device
ASTM	American Society for Testing and Materials
BOD	Biological Oxygen Demand
BP	Boiling Point
CAA	Clean Air Act
CAS Number	Chemical Abstracts Service Number
CEF	Control Equipment Failures
CEMS	Continuous Emissions Monitoring System
CFR	Code of Federal Regulations
CH_4	Methane
CMS	Continuous Monitoring System
CO_2	Carbon Dioxide
CTG	Control Technology Guidelines (EPA, 1978)
CVS	Closed Vent System
CWA	Clean Water Act
DE	Design Evaluation
DOT	Department of Transportation
EC	Air Emissions Control
ED	Estimated Dose
EE	Emissions Estimation
EPC	Emission Potential Concentrations
EPA	U.S. Environmental Protection Agency
F_{bio}	Degradation Factor for biological treatment
Fm	Fraction measured
FDA	Food and Drug Administration
FID	Flame Ionization Detector
FR	Flowrate
gal	Gallon
GC	Gas Chromatography
GGG	subpart GGG to part 63 - NESHAP
H_2O	Water
HAPs	Hazardous Air Pollutants
HCl	Hydrogen Chloride
HDPE	High Density Polyethylene
HON	Hazardous Organic - NESHAP
IDS	Individual Drain System
I&M	Inspection and Maintenance
IWP	Improper Work Practices
Kb	Subpart of NSPS- requirements for storage tanks w/floating roofs
kg	Kilogram

lb	Pound
LDAR	Leak Detection and Repair
M^3	Cubic Meter
M21	Method 21
MACT	Maximum Achievable Control Technology
MDL	Method Detection Limit
MED	Median Effective Dose
MiBK	Methyl isobutyl Ketone
mmHg	millimeters Mercury
MW	megawatts
NAICS	North American Industrial Classification System
NESHAP	National Emission Standard for Hazardous Air Pollutants
NOC	Notification of Compliance
NOCSR	Notification of Compliance Status Report
NPDES	National Pollutant Discharge Elimination System
NSPS	New Source Performance Standards
O_2	Oxygen
O/O	Owner or Operator
P2	Pollution Prevention
Pa	Pascal
PEG	Polyethylene Glycol
PhRMA	Pharmaceutical Research and Manufacturers of America
PL	Production Levels
PMPU	Pharmaceutical Manufacturing Process Unit
POD	Point of Determination
ppm	Parts per million
ppmv	Parts per million volume
ppmw	Parts per million weight
PRV	Pressure Release Valve
PSHAP	Partially Soluble Hazardous Air Pollutants
psi	Pound per Square Inch
PT	Performance Testing
QA/QC	Quality Assistance/Quality Control
RCRA	Resource Conservation and Recovery Act
RE	Removal Efficiences
scfm	standard cubic feet per minute
SHAP	Soluble Hazardous Air Pollutants
SIC code	Standard Industrial Classification
SSM	Startup, Shutdown, or Malfunction
TOC	Total Organic Compounds
tpy	Tons per year
TSS	Total Suspended Solids
TTN	Technology Transfer Network (http://www.epa.gov/ttn/)
VHAP	Volatile Hazardous Air Pollutants
VOC	Volatile Organic Compounds

VP	Vapor Pressure
VS	Vapor Suppression
WMU	Waste Management Unit
WW	Waste Water
WWT	Wastewater Treatment

Chapter 1
Purpose

1.1 Purpose of the Document

This document is intended to help owners and operators of pharmaceutical manufacturing operations understand and comply with the U.S. Environmental Protection Agency's (EPA) air pollution regulations promulgated on September 21, 1998, substantially revised on August 29, 2000 and revised again on August 2, 2001, for the pharmaceutical industry. These regulations contain new emissions standards based on the "maximum achievable control technology" or MACT. On September 21, 1998, EPA published new effluent guidelines, pretreatment standards, and new source performance standards pursuant to the Clean Water Act (CWA). These new CWA provisions are <u>not</u> reviewed in this document.

This document reviews the primary MACT provisions of the regulations, and in many cases, summarizes the regulations in tables or charts to facilitate a quicker review. Within most chapters, questions and answers provided in shaded boxes should help the reader with some of the more complex or confusing components. This document, does not however, attempt to provide interpretations of the rule. In some cases, owners or operators will need to review specific issues relating to their particular production facilities with the appropriate regulating agency.

1.2 Document Organization

The chapters in the document follow the organization of the Pharmaceutical MACT regulations.

Chapter 1 at a Glance

Chapter 2 - *Overview of the Regulations* - provides an overview of the regulations and recreates the table of standards for the four major types of emissions sources: process vents, storage tanks, wastewater, and equipment leaks.

Chapter 3 - *Applicability and Compliance Dates* - takes the reader through the applicability provisions of the regulations and includes several questions and answers to help the reader determine applicability at his/her facility.

Chapter 4 - *Requirements for Storage Tanks* - describes the kinds of tanks subject to regulation and reviews provisions specific to storage tanks, including options for complying with the standards.

Chapter 5 - *Requirements for Process Vents* - describes which vents are subject to regulation, including individual vents that may be subject to a more stringent standard, and discusses the different options available for process vent standards.

Chapter 6 - *Equipment Leaks* - reviews the equipment leaks provisions, including identification of leaking equipment, and monitoring and repair requirements.

Chapter 7 - *Requirements for Wastewater* - explains the wastewater regulation, including standards for vapor suppression, air emissions control, and wastewater treatment.

Chapter 8 - *Initial Compliance Demonstrations and Testing Procedures* - reviews the compliance demonstration requirements that must be followed in demonstrating initial compliance with the regulations. This chapter covers compliance demonstrations for storage tanks, process vents, and wastewater.

Chapter 9 - *Monitoring Procedures* - reviews the monitoring requirements that owners/operators must follow to ensure on-going compliance with the regulations.

Chapter 10 - *Pollution Prevention* - goes over the pollution prevention options that are available to existing sources. The chapter includes examples that show how emissions baselines are calculated. A detailed, "real-life" pollution prevention success story is also described.

Chapter 11 - *Emissions Averaging* - describes the emissions averaging provisions that may be applied to process vents and storage tanks. The chapter provides an example for process vents and an example for tanks.

Chapter 12 - *Recordkeeping* - includes comprehensive tables that describe the recordkeeping requirements in the MACT regulations.

Chapter 13 - *Reporting* - also contains comprehensive tables, specifically for reporting requirements. Three of the tables in the chapter are organized according to the type of report - precompliance, notification of compliance status, and periodic.

1.3 Disclaimer for the Use of this Guide

The reader should note that following the information provided in this document does not shield the facility from enforcement actions taken by the EPA or authorized state agencies. This document provides an overview and "plain English" explanation of the new standards. It is not a substitute for the regulations presented in 40 CFR Part 63, Subpart GGG.